

PRODUCT DESCRIPTION:

NATtrol™ GI (Gastrointestinal) Panel* (qualitative) is formulated with purified, intact cells (bacterial, fungal or parasites) and viral particles. The microorganisms have been chemically modified to render them non-infectious and refrigerator stable. NATGIP-BIO contains 22 x 0.25mL vials of bacterial, fungal, parasite and viral NATtrol™ and 4 x 0.85mL vials of Negative Control as listed in Table 1. The panel members are supplied in a proprietary matrix.

*Pat.: <http://www.zeptometrix.com/patent-information/>

INTENDED USE:

- NATtrol™ GI Panel can be used to develop procedures for verification of performance of molecular assays that detect the presence of bacterial and viral nucleic acids (from organisms listed in Table 1). The panel can also be used for training and evaluation of operator proficiency.

WARNINGS AND PRECAUTIONS:

- NATtrol™ inactivation was carried out on microorganism stocks used to formulate the panel members. The inactivation was verified in a standard microbiological growth protocol.
- This panel contains inactivated microorganisms and materials of animal origin. Safe practices suggest that the controls be considered potentially infectious and to use Universal Precautions when handling.
- Refer to CDC guidelines and local regulations for handling and disposal.
- The stool diluent used in the manufacture of this product contains 0.05% gentamicin sulfate and 0.125% 2-chloroacetamide.
- Heat inactivated Bovine Serum Albumin used in the manufacture of this product meets applicable USDA requirements for abattoir sourced animals, traceability and country of origin. The materials were collected at USDA licensed establishments or legally imported from countries recognized by the USDA as negligible or controlled for risk for Bovine Spongiform Encephalopathy (BSE) and other exotic disease agents. Donor animals were inspected ante and post mortem at the abattoir as required by the USDA.
- Do not use past the expiration date on the label.
- To avoid cross-contamination, use separate pipette tips for all materials.

RECOMMENDED STORAGE:

- NATtrol™ GI Panel should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

- Mix vial vigorously for at least 5 secs.
- Process according to manufacturer's instructions for sample to result assays.
- Extract nucleic acid prior to use in downstream assays that are not sample to result.

LIMITATION:

- FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES**
- Use in accordance with local, state, federal, and accreditation requirements.
- This product is not intended to replace the manufacturer's controls provided with the assay.

EXPECTED RESULTS:

- Each laboratory must evaluate the product and establish their own performance criteria.
- This panel has been tested with the BioFire Diagnostics FilmArray® Gastrointestinal (GI) Panel assay and provides all expected results for the panel members listed in Table 1.








TABLE 1: PANEL MEMBERS

Panel Member	Strain	Panel Member	Strain
Adenovirus Type 41	TAK	<i>G. lamblia</i>	H3
Astrovirus	Recombinant ¹	Norovirus GI	Recombinant ¹
<i>C. cayetanensis</i>	Recombinant ¹	Norovirus GII	Recombinant ¹
<i>C. coli</i>	Clinical isolate	<i>P. shigelloides</i>	Z130
<i>C. difficile</i>	NAP1	Rotavirus	Wa
<i>C. jejuni</i>	Clinical isolate	<i>S. enterica typhimurium</i>	Z005
<i>C. parvum</i>	Iowa	<i>S. sonnei</i>	Z004
<i>E. coli</i>	7.1493; O84:H28; EPEC ²	Sapovirus	Recombinant ¹
<i>E. coli</i>	92.0147; EAEC ²	<i>V. cholerae</i>	Z133; non-toxigenic
<i>E. coli</i>	EDL933; O157	<i>Y. enterocolitica</i>	Clinical isolate
<i>E. coli</i>	EPEC; ST+, LT+	Negative	N/A
<i>E. histolytica</i>	DS4-868		

¹ This analyte only contains a short sequence of the genome, therefore each laboratory must evaluate performance in their assay.

² These strains, 7.1493 and 92.0147, were supplied by Dr. Chobi DebRoy of the E. coli Reference Center, through a license with the Penn State Research Foundation.

PINATGIP-BIO
Revision: 21
Effective Date: 04/17/2024

	Catalog Number		Temperature Limitation
	Batch Code		Expiration Date
	For Research Use Only		Biological Risk
	Manufacturer		

PCA# 24-167
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